Supreme Court, U.S.
FILED

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No. _____

In The

Supreme Court of the United States

October Term, 1997

CRITIKON, INC.,

Cross-Petitioner,

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,

Cross-Respondent.

On Conditional Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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February 5, 1998

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QUESTIONS PRESENTED

1. Did the Court of Appeals for the Federal Circuit err by not following its *en banc* decision in *Kingsdown Medical Consultants v. Hollister, Inc.*, 863 F.2d 867 (Fed.Cir. 1988), holding that as a matter of law a patent applicant's gross negligence does not give rise to sufficient culpability to hold a patent unenforceable on the ground of inequitable conduct?

2. Did the Court of Appeals for the Federal Circuit improperly set aside the district court's fact findings without giving due regard to the district court's findings as required by Rule 52(a), Fed.R.Civ.P.?

STATEMENT PURSUANT TO RULE 29.6

Critikon, Inc., the conditional cross-petitioner here, was the plaintiff-cross appellant below. The affiliates of Critikon, Inc. are Johnson & Johnson, Inc. and Johnson & Johnson Medical, Inc. The successor in interest of Critikon, Inc. is Johnson & Johnson Medical, Inc. Becton Dickinson Vascular Access, Inc., the cross-respondent here, was the defendant-appellant below and is the wholly owned subsidiary of Becton Dickinson and Company.

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CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Critikon, Inc. ("Critikon") submits this conditional cross-petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). Becton Dickinson Vascular Access, Inc. ("Becton Dickinson") submitted a petition for a writ of certiorari in this action on December 23, 1997, docketed on January 6, 1998 as No. 97-1095 (hereinafter "Becton Dickinson's petition"). Critikon opposes Becton Dickinson's petition in a separately filed opposition. However, in the event that Becton Dickinson's petition is granted, Critikon believes that the instant conditional cross-petition should also be granted.

OPINIONS BELOW

The August 12, 1997 opinion of the Federal Circuit is reported at 120 F.3d 1253 (Fed.Cir. 1997), and is reproduced beginning at Appendix page 2a of Becton Dickinson's petition. The July 18, 1994 memorandum opinion of the district court is reproduced beginning at Appendix page 19a of Becton Dickinson's petition.

JURISDICTION

The Federal Circuit denied petitions for rehearing and suggestions for rehearing *en banc* on September 24, 1997. Becton Dickinson's petition for a writ of certiorari was docketed on January 6, 1998, as No. 97-1095. The

instant cross-petition is timely filed pursuant to Rule 12.5, Sup.Ct.R. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Rule 52(a) of Title 28, Fed.R.Civ.P., provides in pertinent part:

> Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witness. . . .

STATEMENT OF THE CASE

In this action for patent infringement, Critikon charged Becton Dickinson with infringing two patents, U.S. Patent No. 4,952,207 (and the reissue of that patent, No. RE 34,416) issued to Lemieux (hereinafter the "Lemieux patents"), and U.S. Patent No. 4,978,344, issued to Dombrowski (hereinafter the "Dombrowski patent"). The Lemieux and Dombrowski patents were found valid by the Federal Circuit and the Federal Circuit found that Becton Dickinson willfully infringed both patents.

The subject of this petition is directed to the Federal Circuit's erroneous conclusion that the Lemieux patents are unenforceable due to the alleged inequitable conduct – *i.e.*, fraud – practiced on the United States Patent and Trademark Office (hereinafter "PTO") by the Critikon attorneys that prosecuted the Lemieux patents.

I. Background

The Lemieux patents are directed to medical devices called intravenous catheters. Intravenous catheters consist of thin plastic tubes that are inserted into a hospital patient's veins so that medicinal fluids can be introduced into the body. (3a, 21a). To permit insertion into a vein, catheters are mounted over steel introducer needles. After the catheter-needle assembly is inserted by a healthcare worker, the needle is withdrawn, leaving the catheter within the vein. (3a, 21a). This procedure, however, subjects the healthcare worker to the danger of accidental needlesticks from the exposed needle. Due to the increased risk of exposure to AIDS by way of accidental needlesticks, the demand for improved safety catheters became the overwhelming issue in hospitals in the late 1980's.

After extensive research and development, Critikon invented the safety catheter described in the Lemieux patents. The Lemieux safety catheter has a "needle guard" that is positioned over the tip of the needle as the needle is withdrawn from the catheter to protect healthcare workers from accidental needlesticks. (3a, 23a). As a result of its research and development, Critikon was the very first company to introduce a viable, commercial safety catheter for use in hospitals, a product referred to as the ProtectIV® safety catheter system. Over the years, Critikon's ProtectIV® safety catheter has saved scores of lives by eliminating the possibility of accidental needlesticks.

II. The Proceedings In The District Court

After a highly fact intensive case involving over 1300 pages of trial testimony, 8000 pages of deposition testimony, and 1000 exhibits, the district court held that Becton Dickinson had wholly failed to prove that there was any inequitable conduct associated with Critikon's prosecution of the Lemieux patents. In the trial court, Becton Dickinson argued that Critikon's attorneys had intentionally withheld a prior art patent, the McDonald '718 patent (hereinafter, "the McDonald patent"), from the PTO during the prosecution of the Lemieux patents. (50a).

Critikon responded by showing that Critikon's failure to cite the McDonald patent to the PTO was not done with any intent to mislead or deceive the PTO, and that, in any event, the McDonald patent was not a material reference. (51a). The district court agreed with Critikon. On the issue of intent, the district court specifically found that Critikon's actions were "not intentional nor designed to mislead the patent examiner." (51a). In so holding, the district court was persuaded by the testimony of Critikon's witnesses establishing that the McDonald patent was "substantially different than . . . the Lemieux patents." (52a). The district court's conclusion on the intent issue was based not only on the credibility of Critikon's witnesses, (52a), but also on the lack of credibility of Becton Dickinson's expert witness, Mr. Fischell, who was found by the district court to be "ambivalent" and unable to withstand cross-examination. (26a-27a, 35a, 39a, 46a-47a).

On the materiality issue, the district court again agreed with Critikon. Specifically, the district court was "persuaded by the testimony of both expert witnesses that the McDonald patent teaches a device that is substantially different than that contemplated by the Lemieux patents." (51a-52a). This conclusion, once again, was grounded in the district court's credibility findings, and on the admissions of Becton Dickinson's expert witness, Mr. Fischell. Mr. Fischell testified that the McDonald patent was significantly different from the Lemieux patents. He freely admitted that the McDonald patent was "complex," "expensive," not commercially usable as compared to the far more practical and less expensive design of Lemieux, and thus, not material to the patentability of Lemieux.

III. The Federal Circuit Decision

On appeal, the Federal Circuit reversed the district court and found that Critikon had committed inequitable conduct in the prosecution of the Lemieux patents. In finding wrongful intent, the Federal Circuit did not find that there was any actual, specific intent to deceive. Rather, the Federal Circuit improperly based its finding of wrongful intent not on what Critikon knew, but rather on what it *"should have known."* (emphasis added). (6a). Based on that erroneous legal standard, the Federal Circuit overturned the district court. In doing so, the Federal Circuit not only misstated the law, but also erroneously rejected the district court's findings and credibility determinations on the issue of intent. (8a). On the issue of materiality, the Federal Circuit again rejected the district court findings on credibility, and in reversing the district

court, improperly relied exclusively on the thoroughly discredited testimony of Mr. Fischell. (*Compare* 10a-11a *with* 26a-27a, 35a, 39a).

REASONS FOR GRANTING THE PETITION

I. The Court Of Appeals Erred By Not Following Its Own *En Banc* Decision In *Kingsdown Medical*

Congress created the Federal Circuit for the purpose of establishing a uniform body of patent law. After the creation of the Federal Circuit, there was considerable disagreement within that Court as to what legal standard governs the level of wrongful intent needed for a finding of inequitable conduct. In one line of cases, the Federal Circuit held that gross negligence alone was sufficient to establish the required degree of culpability. *See, e.g., Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed.Cir. 1984). Indeed, the *Driscoll* court explicitly held that wrongful intent can be found where an applicant "should have known" that a reference was material. *Driscoll*, 731 F.2d at 885. In another line of cases, the Federal Circuit held that gross negligence was insufficient as a matter of law to support a finding of inequitable conduct. *See, e.g., In re Harita*, 847 F.2d 801, 809 (Fed.Cir. 1988); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n. 9 (Fed.Cir. 1987).

As is often the case when diverging rules of law appear, one emerged as the clear winner in the Federal Circuit's *en banc* decision in *Kingsdown Medical Consultants v. Hollister, Inc.*, 863 F.2d 867 (Fed.Cir. 1988). In *Kingsdown*, after a thorough analysis of the conflicting precedents, the Federal Circuit rejected the line of cases

holding that "gross negligence" was sufficient to support a finding of wrongful intent and, in doing so, specifically cited and rejected the legal standard set forth in *Driscoll*. 863 F.2d at 876. Rather, the Federal Circuit held in *Molins PLC v. Textron*, 48 F.3d 1172 (Fed.Cir. 1995), that a "specific intent" to withhold "a known material" reference is necessary before inequitable conduct can be found. 48 F.3d at 1181.

Since *Kingsdown*, and until the Federal Circuit's decision in this case, the legal standard governing the level of intent necessary to find inequitable conduct was well-settled. *See, e.g., Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed.Cir. 1996); *Scripps Clinic & Research Found. v. Genetech, Inc.*, 927 F.2d 1565, 1573 (Fed.Cir. 1991); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed.Cir. 1990); *Hoffman-La Roche v. Lemmon Co.*, 906 F.2d 684, 688 (Fed.Cir. 1990).

In this case, however, the *Critikon* panel violated the settled law of *Kingsdown* by clearly misstating the law and by relying on *Driscoll*. The Federal Circuit held:

> [I]ntent may be inferred where a patent applicant knew, *or should have know*[*n*], that withheld information would be material to the PTO's consideration of the patent application. *Driscoll v. Cebalo* [citation omitted].

(6a) (emphasis added). Plainly, the *Critikon* panel erred in failing to follow the rule of *Kingsdown*, and further erred in reverting to the discredited "should have known" standard of *Driscoll*.

The Federal Circuit disregarded nearly nine years of consistent precedent, it ignored its own *en banc* decision

in *Kingsdown*, and it clearly erred in resurrecting the long rejected rule of *Driscoll*. This abrupt and unexplained change in direction has created a state of uncertainty in the law, an uncertainty that has widespread adverse ramifications justifying this Court's review.

At the time the Federal Circuit was created, the importance of a uniform body of patent law was universally recognized. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, ___, 116 S.Ct. 1384, 1396 (1996). Since that time, technological advances have underscored the importance of patent protection, and likewise, the importance of some reasonable measure of predictability in knowing when that protection might be lost on account of a finding of inequitable conduct. This issue is of special importance because the Federal Circuit has the exclusive jurisdiction over appeals from all United States District Courts in patent cases. *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89, 113 S.Ct. 1967, 1971 (1993).

When there is significant disagreement between two lines of Federal Circuit cases, as there is here, the confusion caused by the inconsistent decisions affects inventors and investors, as well as the public that can attain significant benefits from research and development that is based on the ability to obtain sound, enforceable patent protection. *See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, ___ U.S. ___, ___, 117 S.Ct. 1040, 1045 (1997). For all of these reasons, this Court should grant the instant petition for a writ of certiorari.

II. The Federal Circuit Failed To Follow Rule 52(a), Fed.R.Civ.P.

When reviewing a district court's findings of fact, Rule 52(a) of the Federal Rules of Civil Procedure provides:

> Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witness.

This Court has held that Rule 52(a), Fed.R.Civ.P., means that if the district court's account of the evidence is plausible in light of the entire record, the district court's decision must stand. *Anderson v. City of Bessemer City*, 470 U.S. 564, 573-4, 105 S.Ct. 1504, 1511 (1985). An appellate court may not substitute its own interpretation of the facts in place of those found by the district court, and it is particularly inappropriate for an appellate court to draw sinister conclusions from actions that the district court found innocent. *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 857-858, 102 S.Ct. 2182, 2190 (1982) (*citing United States v. Real Estate Bds.*, 339 U.S. 485, 495, 70 S.Ct. 711, 717 (1950)). In sum, an appellate court cannot reverse the findings of the trier of fact simply because it is convinced that it would have decided the case differently. *Anderson*, 470 U.S. at 573-4, 105 S.Ct. at 1511.

The Federal Circuit plainly violated Rule 52(a) by substituting its own findings for those of the district court when it reversed the district court's finding of no inequitable conduct. Indeed, the Federal Circuit never held the district court's factual determinations to be

"clearly erroneous" as required by Rule 52(a), Fed.R.Civ.P. Rather, the Federal Circuit improperly substituted its own findings for those of the district court.

On the intent issue, the Federal Circuit held that "[o]ur review of the record leads us to conclude that Critikon" intended to mislead the PTO. (6a). But the Federal Circuit did so without showing any deference at all to the district court's findings that, based on a careful weighing of the testimony, Critikon's actions were "not designed to mislead the patent examiner." (51a-52a). The Federal Circuit clearly violated Rule 52(a), Fed.R.Civ.P., by disregarding the district court's findings that Critikon's actions were innocent and instead wrongly substituting its own interpretation of the facts by finding the innocent actions of Critikon to be far "more sinister" than the district court believed them to be. *See Inwood Labs.*, 456 U.S. at 857-58, 102 S.Ct. at 2190. At best, the Federal Circuit's view of the evidence is as plausible as the district court's view, in which case "the [district court's] choice . . . cannot be clearly erroneous." *Anderson*, 470 U.S. at 574, 105 S.Ct. at 1511.

On the issue of materiality, the district court's finding that the McDonald patent was not material was explicitly based on the district court's findings concerning the credibility of the parties' expert witnesses. The district court, after hearing the testimony and cross-examination of the parties' expert witnesses, was "persuaded by the testimony of both expert witnesses that the McDonald patent teaches a device that is substantially different than that contemplated in the Lemieux patents." (51a-52a). In these circumstances, this Court has stated that when factual findings are based on the credibility of witnesses:

> Rule 52(a) demands even greater deference to the trial court's findings; for only the trial judge can be aware of the variations in demeanor and tone of voice that bear so heavily on the listener's understanding of and belief in what is said.

Anderson, 470 U.S. at 575, 105 S.Ct. at 1512. Moreover, according "greater deference" to a district court's findings is especially appropriate where those findings are based, as they are here, on the selection of "the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story. . . . " *Id.* When a trial judge makes this type of determination, as he did here, there "can virtually never be clear error." *Id.*

The Federal Circuit, however, afforded the district court's decision no deference by finding that the McDonald patent was material to the patentability of the Lemieux patents. In making its materiality determination, the Federal Circuit relied on the testimony of Mr. Fischell, Becton Dickinson's expert witness, (10a-11a), who the district court found was wholly lacking in credibility. (26a-28a, 34a-35a, 39a, 43a-44a, 50a-52a). Specifically, the district court found that Mr. Fischell was frequently ambivalent and wholly unable to withstand cross-examination. (26a-28a, 34a-35a, 39a, 43a-44a, 50a-52a). By relying on a witness that the district court found to be completely lacking in credibility and disregarding the witnesses found to be credible, the Federal Circuit clearly violated Rule 52(a), Fed.R.Civ.P., warranting the grant of certiorari by this Court.

This is not a case involving mere factual error. Rather, it is a case where the court below wholly disregarded the appropriate standard of review that governs all of the United States Courts of Appeals. When, as in this case, the appellate court misapprehends and misapplies the clearly erroneous standard and fails to expressly find that the district court's findings were clearly erroneous, this Court should grant certiorari. *Citibank, N.A. v. Wells Fargo Asia, Ltd.*, 495 U.S. 660, 668, 110 S.Ct. 2034, 2039 (1990); *Anderson*, 470 U.S. at 566, 105 S.Ct. at 1508; *Inwood Labs.*, 456 U.S. at 853, 102 S.Ct. at 2188; *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 108, 89 S.Ct. 1562, 1568 (1969).

CONCLUSION

For the foregoing reasons, Critikon's conditional cross-petition for a writ of certiorari should be granted.

February 5, 1998

Respectfully Submitted,

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